

Spring 3-2013

Spring 2013

Center for Research & Grants

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Recommended Citation

Center for Research & Grants, "Spring 2013" (2013). *Research Matters*. Book 8.
<http://scholarlycommons.baptisthealth.net/bg-research-matters/8>

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Center for Research & Grants

8th Annual BHSF Research Conference

The Center for Research & Grants is hosting the **8th Annual BHSF Research Conference, Clinical Research: Key to Quality Practice on April 12 at Jungle Island**. The conference is designed to engage healthcare providers in research and evidence-based practice activities that improve the quality of patient care and enhance organizational efforts to provide clinically excellent, compassionate care.

Guest speakers include Dr. **Louis F. Fogg**, part of the Board of Directors for the American Statistical Association (Chicago Chapter) and their past president. Professor for College of Nursing and Rush Medical College at Rush University and a visiting professor at the University of Illinois at Chicago. Has provided statistical expertise on over 25 NIH funded studies and has over 120 peer-reviewed publications. Research interests includes mathematical modeling and research design in nursing research.



Joining Dr. Fogg as a guest speaker is Dr. **Rosa M. Gonzalez-Guarda**, an Assistant Professor at the University of Miami School of Nursing and Health Studies and a Robert Wood Johnson Foundation Nurse Faculty Scholar. She served as a committee member on the landmark Institute of Medicine Report on the Future of Nursing and currently serves on the steering committee for the FL Action Coalition for the Future of Nursing. Her research focuses on behavioral health disparities affecting Hispanics and culturally tailored interventions to address these.

Registration is available through BHU (BHSF employees only) and non-BHSF employees can visit <http://8thannualcrgconference.bpt.me/> to register.

VOLUME 2, ISSUE 1

SPRING 2013 EDITION

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FINANCIAL CONFLICT OF INTEREST POLICY FOR RESEARCH

Baptist Health South Florida has revised the policy 1300.03 – Individual Financial Conflicts of Interest (FCOI) in Research. According to this policy and the Public Health Service (PHS) Financial Conflict of Interest (FCOI) regulations for research, we are requiring that investigators be re-trained immediately. As such, investigators who have completed the FCOI training via the CITI website; on or prior to February 5, 2013 are required to be re-trained.

1. Re-taking the CITI Conflicts of Interest Course
2. Attending a classroom session (Dates, Times and Locations will be forthcoming)

The deadline for re-training is April 30, 2013.

If you have any questions, please contact, Dawn Prospect, Research Compliance Specialist at 786-527-9026 or

Researchcompliance@baptisthealth.net

The options for re-training include:

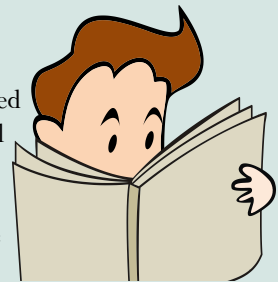
Registration for Research Trials on www.ClinicalTrials.gov

By Jacqueline Mejias, LPN, CCRC, CCRP

This article offers guidance and support to researchers who must register and report clinical research trials to ClinicalTrials.gov, a database of clinical research trials conducted in the United States and around the world.

WHAT IS CLINICALTRIALS.GOV?

ClinicalTrials.gov is a registry of federally and privately supported research studies conducted in the United States and worldwide. Each entry is provided by the sponsor and includes a brief summary of the protocol together with the purpose, recruitment status, and criteria for patient participation. Trial locations and specific contact information are provided to assist enrollment. Some entries provide summary study results, including number of participants starting and completing the trial, baseline characteristics, outcome measures, and adverse events information. ClinicalTrials.gov is a free service of the U.S. National Institutes of Health (NIH), developed by the National Library of Medicine.



WHY REGISTER?

Required by law. Section 801 of the Food and Drug Administration (FDA) Amendments Act mandates the registration with ClinicalTrials.gov of certain clinical trials of drugs (including biological products) and medical devices subject to FDA regulations for any disease or condition. Trials that must be registered under the **FDA Amendments Act of 2007 (FDAAA)** are called “Applicable Clinical Trials.”

Under the statute, these trials generally include:

Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and **Trials of Devices:** Controlled trials with health outcomes, other than small feasibility studies, and pediatric post-market surveillance.

ClinicalTrials.gov accepts registration of all clinical trials (1) approved by a human subject review board and (2) conforming to the regulations of the appropriate national health authorities. Both

Interventional and observational studies are accepted. Trials can be registered at any time, but many policies require registration prior to the enrollment of the first participant.

Required for journal publication. The International Committee of Medical Journal Editors (ICMJE) requires trial registration as a condition for publication of research results generated by a clinical trial. <http://www.icmje.org>

Investigators should go to <http://prsinfo.ClinicalTrials.gov> for detailed information on creating an account and also contact their clinical research coordinator for assistance in registering their trial. NIH encourages registration of ALL trials whether required under the law or not, and the International Committee of Medical Journal Editors (ICMJE) advises that those who are uncertain whether their trial meets the ICMJE definition of eligible trials should consider registering if they wish to seek publication in an ICMJE journal.

Since responsibility for registering trials lies with the lead sponsor of the clinical study, most industry sponsored trials will be registered by the sponsor, which can be a pharmaceutical company or Clinical Research Organization (CRO). Investigator initiated studies need to be registered by the investigator prior to study enrollment.



Research Exchange: The use of IV Acetaminophen in a Multimodal Pain Approach in Bariatric Surgery
- Does it Affect Opioid Requirements? Presentation by **Dr. Anthony Gonzalez**

March 7th 6:00 - 7:00 p.m. • BH Classroom 5

You may register at BHU or through our CME department.

For more information • contact CRGResearch@baptisthealth.net or 786-594-6713

Nursing Research Spotlight

Forming Research Teams

By Maria M. Ojeda, ARNP, MSN, MPH, NP-C

I recently ran across an article in the British daily newspaper *The Telegraph* that intrigued me. The article focused on the demise of the “lone scientist” toiling away in hopes of a great discovery and the realization that interdisciplinary teams of researchers and scientists will form the basis of future discoveries. The author cited that today’s scientific problems are far too “multifaceted and vast” to be solved by one individual, rather there is a need for the inclusion of a diversity of viewpoints and approaches towards the resolution of a single problem (Donald, 2012). While the article’s spotlight was on the basic sciences, the same holds true for health care research. Clinicians today are faced with the care of patients that suffer not only from medical conditions and disease states but also from psychosocial, economic and cultural barriers to self care. By designing and implementing research projects that account for a multitude of factors, interdisciplinary research teams may be able to assist in the resolution of complex clinical problems and ultimately contribute a positive impact on the quality of care delivered. Forming an interdisciplinary research team is not difficult but there are a few guidelines that you may want to know (Bennett, Gavin, Levine-Finley, 2010):



1. Clearly identify your specific area of interest or the problem you wish to address.
2. Bring together a diverse group that includes individuals with expertise on a particular aspect of the problem. For example, a research team to address medication errors may need to include: a physician, nurse, pharmacist, information technologist, and a department manager.
3. Identify roles and responsibilities for each team member early on.
4. Allow for conflicting points of view, especially during the research design phase.
5. Agree on a method of sharing credit and authorship of the research, initially and throughout the project.

Finally, keep in mind, you do not have to be in a position of authority or formal leadership to build a research team nor do you have to be an “expert” at designing research. You must however, have a strong desire to make a difference, to contribute your knowledge, insight, and energy towards impacting care and most importantly, the improvement of outcomes. The Baptist Health of South Florida, Inc. Center for Research and Grants is ready to assist you! Let our dedicated team of research design and funding professionals help your research team reach its goals.

Bennett, L., Gadlin, H., Levine-Finley, M. (2010). Collaboration and team science: a field guide. Retrieved from https://ccrod.cancer.gov/confluence/download/attachments/47284665/TeamScience_FieldGuide.pdf

Donald, A. (September, 2012). *How many scientists does it take to make a discovery?* Retrieved from <http://www.telegraph.co.uk/science/9548376/How-many-scientists-does-it-take-to-make-a-discovery.html>

SAVE THE DATE

2013 BHSF Research Summit

Friday, October 4th, 2013

Miami Marriott Dadeland

Target Audience: Research physicians, clinical research coordinators, research administrators and nurses.



EDUCATIONAL EVENTS

Date & Time	Event	Location
Thursday, 3/7/2013 6:00 pm - 7:00 pm	Research Exchange: The use of IV Acetaminophen in a Multimodal Pain Approach in Bariatric Surgery - Does it Affect Opioid Requirements?	BHM - Classroom 5
Thursday, 3/7/2013 12:00 pm - 1:30 pm	Research Webinar: Increasing Predictable Site Enrollment Success	BHM - Oasis II (Pineapple)
Friday, 4/5/2013 7:30 am - 8:30 am	Research Rounds: Delivering Successful Podium and Poster Research Presentations	BHM - Classroom 2
Tuesday, 4/9/2013 12:00 pm - 1:00 pm	Research Webinar: Stand Out During Site Selection Process	T & C Conference Room 2
Thursday, 5/2/2013 6:00 pm - 7:00 pm	Research Exchange: TBA	BHM - Classroom 5
Tuesday, 5/21/2013 12:00 pm - 1:00 pm	Research Webinar: Deviations and the Regulations - What Matters Most	T & C Conference Room 2